

Appendix 2: Characteristics of studies included in the systematic review of randomised trials of endometrial destruction devices for HMB [posted as supplied by author]

<b>Paper/ Number of women randomised</b>	<b>Patients <sup>1</sup></b>	<b>Intervention <sup>2</sup></b>	<b>Stated key outcome measures</b>	<b>Patient satisfaction and how it was measured</b>
<b>Second vs second generation ED</b>				
Clark <sup>31</sup> N=81 Raw data available	Women with HMB unresponsive to medical treatment. No organic pathology, uterine cavity length, less than 11 cm, no previous open myomectomy, endometrial ablation or resection or classical caesarean delivery.	Bipolar radio frequency (Novasure) v Thermal balloon (Thermachoice) Office setting, local anaesthetic	Amenorrhoea rate Disease specific quality of life questionnaire Generic quality of life questionnaire Sexual function Technical feasibility Intra- and post-operative complications Patient acceptability Anxiety Operative and ablative time Follow-up reported at 3,6 and 12 months	Women were asked to compare their HMB with before treatment.  Answers given using the following scale. Much better A little better Same Worse
Penninx <sup>32</sup> n=160	HMB as defined by PBAC score >150. Fibroids and polyps >2cm, uterine surgery (other than Caesarean delivery) and coagulopathies excluded.	Bipolar radio frequency (Novasure) v Free-fluid (BEI Medical Systems)	Amenorrhoea rate PBAC score Satisfaction Complications Reinterventions Follow-up reported at 1,6 and 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Completely satisfied Satisfied Doubtful Unsatisfied
Sambrook <sup>33</sup> n=320 Raw data available	Women with HMB with no organic pathology or obstructing fibroids.	Microwave v Thermal balloon (Thermachoice)	Satisfaction PBAC score Dysmenorrhea Generic quality of life questionnaire Acceptability Pain due to surgery Follow-up reported at 2 weeks,6 and 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Totally satisfied Generally satisfied Slightly satisfied Slightly dissatisfied Generally dissatisfied Totally dissatisfied
Bongers <sup>34</sup> N=126 Raw data available	HMB as defined by PBAC score >150 and normal uterine cavity 6-11cm in	Bipolar radio frequency (Novasure) v	Amenorrhoea rate PBAC score Satisfaction	Women were asked how satisfied they were with their treatment.

<sup>1</sup> Information about fibroids/ uterine pathology provided in this column to allow assessment of generalisability of the trials.

<sup>2</sup> TCRE – TransCervical Resection of the Endometrium

ELITT – Endometrial Laser Intrauterine Thermal Therapy

	length. Uterine surgery (other than Caesarean delivery) and coagulopathies excluded.	Thermal balloon (Thermachoice)	Dysmenorrhea Complications Reinterventions Follow-up reported at 3,6 and 12 months	Answers were given using the following scale: Completely satisfied Satisfied Doubtful Unsatisfied
Abbott <sup>35</sup> N=57 Raw data available	HMB as defined by PBAC score >150 and normal uterine cavity <12cm in length	Bipolar radio frequency (Novasure) v Thermal balloon (Cavaterm)	Amenorrhoea rate Satisfaction Acceptability Quality of life questionnaire Sexual health Complications Reinterventions Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Very satisfied Satisfied Dissatisfied Very dissatisfied
<b>First vs second generation ED</b>				
Brun et al 2006 <sup>36</sup> Raw data available N = 62	Women with HMB unresponsive to medical treatment. Submucous fibroids excluded, other fibroids included (further details not given)	TCRE v Thermal balloon (Cavaterm)	Satisfaction PBAC score post-operatively Operative time Discharge time Complication rate Resumption of normal activities Follow-up reported at 6 and 12 months; IPD at 3 months also received	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Excellent Good Moderate Bad
J Cooper 2004 <sup>37</sup> Raw data available N = 322	Women with documented HMB due to benign causes. Fibroids excluded if larger than 3cm.	Rollerball v Microwave	Satisfaction PBAC score Amenorrhoea rate Duration of procedure Anaesthesia Type of anaesthesia Device-related complications Adverse events Dysmenorrhoea Quality of life questionnaire (SF-36) Acceptability of treatment Follow-up reported at 3,6 and 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Very satisfied Satisfied Dissatisfied
Perino et al 2004 <sup>16</sup> N = 116	Women with abnormal uterine bleeding. Not stated if fibroids were	TCRE v ELITT	Satisfaction Bleeding status Intraoperative complication rate	Women were asked how satisfied they were with their treatment

	excluded.		Duration of procedure Pain Further treatment with hysterectomy Follow-up reported at 12 months and 3 years	Answers were given using the following scale: Very satisfied Satisfied Dissatisfied
Duleba et al 2003 <sup>17</sup> N = 279	Women with HMB due to benign causes. Fibroids excluded if larger than 2cm.	Rollerball v Endometrial cryoablation	Satisfaction PBAC score Bleeding Pain Adverse events Anaesthesia Pre Menstrual Symptoms Follow-up reported at 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Very Slightly Not at all
Hawe et al 2003 <sup>38</sup> Raw data available N = 72	Women with dysfunctional uterine bleeding requesting conservative surgical management of their condition. Fibroids excluded.	Nd: Yag Laser v Thermal Balloon (Cavaterm)	Satisfaction Amenorrhoea rate Effect on blood loss Quality of life Sexual activity Acceptability of procedure Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Very satisfied Moderately satisfied Dissatisfied Very dissatisfied
Van Zon-Rabelink et al 2004 <sup>39</sup> Raw data available N = 139	Women with dysfunctional uterine bleeding. IPD showed that fibroids were included; exact eligibility details regarding this parameter not given in paper.	Rollerball v Thermal Balloon	Satisfaction Menstrual blood loss Quality of life Menstrual status Follow-up reported at 6 and 12 months and 2 years	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Satisfied Not satisfied
J Cooper et al 2002 <sup>14</sup> N = 265	Women with symptomatic HMB. Fibroids excluded	Wire loop resection + Rollerball v Bipolar radiofrequency (NovaSure)	Satisfaction PBAC score Procedure time Sedation Intraoperative complications Postoperative complications Follow-up reported at 6 and 12 months	Women were asked how satisfied they were with their treatment.  No precise information was given on the scale used to answer this question and IPD was not received. Percentage of women very satisfied or satisfied was quoted.
Pellicano et al 2002 <sup>40</sup> N = 82	Women with HMB unresponsive to medical treatment. Fibroids	TCRE v Thermal Destruction	Satisfaction Operative time Discharge time	Women were asked how satisfied they were with their treatment

	excluded.	(Cavaterm)	Complication rate Re-intervention rate Resumption of normal activities Follow-up reported at 3 and 12 months and 2 years	Answers were given using the following scale: Excellent Good Moderate No improvement
Corson et al 2001 <sup>15</sup> N = 276	Women with HMB due to benign causes. Fibroids excluded if larger than 4cm.	Rollerball v Hydroablator (HTA)	Quality of life Reduction in PBAC score Amenorrhoea rate Adverse events Need for further surgery Operative complications Follow-up reported at 6 and 12 months	No comparable measure.
Soysal et al 2001 <sup>41</sup> N = 96	Menorrhagic women over 40 with a mobile myomatous uterus smaller than 12 week pregnancy. Fibroids excluded if larger than 3cm.	Rollerball v Thermal Balloon	Satisfaction Menstrual blood flow reduction Duration of procedure Complication rates Post-operative pain scores Amenorrhoea rates Follow-up reported at 12 months	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Very satisfied Satisfied Dissatisfied
Corson et al 2000 <sup>42</sup> N = 276	Women with HMB, without organic uterine disease, who failed or poorly tolerated medical therapy. Fibroids excluded if larger than 2cm.	TCRE + Rollerball v Thermal Balloon (Vesta)	PBAC scores Amenorrhoea Adverse events Quality of life Follow-up reported at 12 months and 2 years	No comparable measure.
K Cooper et al 1999 <sup>12</sup> Raw data available N = 263	Women referred for endometrial destruction surgery. Fibroids included; exact eligibility details regarding this parameter not given in paper.	TCRE + Rollerball v Microwave	Satisfaction Acceptability of treatment Menstrual Status Quality of life Morbidity Duration of procedure Intraoperative complications Postoperative pain relief Postoperative stay. Absence from work Follow-up done reported at 12 months, 2 years and 5 years	Women were asked how satisfied they were with their treatment.  Answers were given using the following scale: Totally satisfied Generally satisfied Fairly satisfied Fairly dissatisfied Generally dissatisfied Totally dissatisfied
Meyer et al 1998 <sup>9</sup>	Women with HMB.	Rollerball	Satisfaction	Women were asked how satisfied

Raw data available N = 275	Fibroids excluded.	v Thermal Balloon (Thermachoice)	Improvement in dysmenorrhoea symptoms Inability to work PBAC score Complication rate Duration of procedure Requirement for additional surgery Follow-Up done at 3,6 and 12 months	they were with their treatment  Answers were given using the following scale: Very satisfied Satisfied Not satisfied
Romer et al 1998 <sup>43</sup> N = 20	Women with recurrent, therapy refractory HMB. Fibroids excluded (Intrauterine abnormalities excluded, so assumed this included fibroids).	Rollerball v Thermal Balloon (Cavaterm)	Amenorrhoea/ Hypomenorrhoea rate Follow-up reported at 12 months	No comparable measure.